electrons which are then accelerated toward the anode 24. The anode 24 attracts the electrons, but passes them through its central aperture toward the target assembly 26. The controller 12C controls the power supply 12A to dynamically adjust the cathode voltage, the electron beam current, and temporal parameters, or to provide pre-selected voltage, beam current, and temporal parameters.

Also illustrated, is an alternative electron beam generator which includes a photoemitter 22 irradiated by a light source 56, such as a diode laser or LED, powered by a driver 55. The light is focused on the photoemitter 22 by a focusing lens 58.

In the illustrated embodiment, external telemetry device 52 and telemetry network 12E cooperate to permit external control (dynamic or predetermined) control over the power supply 12A and temporal parameters. In embodiments when the housing 12" is not implanted, but where only probe 14 extends into a patient's body, the controller 12C may directly be used to control operation and in that case there is no need for network 12E.

FIGS. 5 and 6 show a diagrammatic view of radiation treatment apparatus 200 including a flexible probe 214. The apparatus 200 includes a high voltage source 218, a laser (or other optical) source 220, a probe assembly 214, and a radiation source assembly 226. According to one aspect of the invention, the apparatus 200 provides the required flexibility, without using strong magnetic fields, by locating electron source components 222, 223 and accelerator 224 near the target 228 in the distal end of the probe 214. The probe assembly 214 couples both the laser source 220 and the high voltage feed 218 to the radiation source assembly 226. Preferably, the probe assembly includes flexible fiber optical cable 202 enclosed in a small-diameter flexible metallic tube 204.

The radiation source assembly 226, which can be for example 1 to 2 cm in length, extends from the end of the probe assembly 214 and includes a shell which encloses the target 228. According to one embodiment, the radiation source assembly 226 is rigid in nature and generally cylindrical in shape. In this embodiment the cylindrical shell enclosing the radiations source assembly 226 can be considered to provide a housing for the electron beam source as well as a tubular probe extending from the housing along the electron beam path. The inner surface 226A of the assembly 45 226 is lined with an electrical insulator, while the external surface of the assembly 226 is electrically conductive. According to a preferred embodiment, the radiation source assembly is hermetically sealed to the end of the probe assembly 214, and evacuated. According to another embodiment, the entire probe assembly 214 is evacuated.

The terminal end 202A of the fiber optical cable 202 is preferably coated, over at least part of its area, with a semitransparent photoemissive substance such as, Ag—O—Cs, thus forming a photocathode 222. A high voltage conductor 208, embedded in the fiber optical cable 202, conducts electrons to the cathode 222 (if necessary), the electron multiplier 223 and the accelerator 224 from the high voltage source 218. Similarly, the flexible tube 204 couples a ground return from the target 228 to the high voltage source 218, thereby establishing a high voltage field between the cathode 216 and the target 228. The fiber optical cable 202 acts as an insulating dielectric between the high voltage conductor 208 and the grounded flexible tube 204.

In order to eliminate scattering of the light in the fiber 65 optic cable 202 by the high voltage wire 208, the fiber optic cable 202 can have an annular configuration. The light from

the laser 220 travels down the annular core of the fiber optic cable 202. Cladding can be provided on each side of the core having an index of refraction so as to reflect the light beam incident on the interface back into the core. The grounded flexible metal tube 204 can surround the outer cladding.

As in previously described embodiments, the target 228 can be for example, beryllium, (Be), coated on one side with a thin film or layer 228A of a higher impedance element, such as tungsten (W) or gold (Au).

In operation, the small semiconductor laser 220 shining down the fiber optical cable 202 activates the transmissive photocathode 222 which generates free electrons 216. The high voltage field between the cathode 222 and target 228 accelerates these electrons, thereby forcing them to strike the surface 228A of target 228 and produce x-rays. In order to generate, for example, 20 uA of current from an Ag—O—Cs photocathode 222 with a laser 220 emitting light at a wavelength of 0.8 m, the 0.4% quantum efficiency of this photocathode 222 for this wavelength requires that the laser 220 emits 7.5 mW optical power. Such diode lasers are readily commercially available. According to the invention, the photoemissive surface which forms cathode 222 can, in fact, be quite small. For example, for a current density at the cathode 222 of 1 A/cm<sup>2</sup>, the photoemitter's diameter need only be approximately 50 µm.

One difficult fabrication aspect of this invention is the fabrication of the photocathode 222, which for practical substances, with reasonable quantum efficiencies above  $10^{-3}$ , should be performed in a vacuum. This procedure can be carried out with the fiber optical cable 202 positioned in a bell jar, where for example, an Ag—O—Cs photosurface is fabricated in the conventional manner. Subsequently, without exposure to air, the optical cable 202 can be inserted into the tube 204. The end 202B can be vacuum sealed to the flexible tube 204.

In the above embodiments, the probe 14 or 214, along with its associated target 26, or 228, can be coated with a biocompatible outer layer, such as titanium nitride on a sublayer of nickel. For additional biocompatibility, a sheath of, for example, polyurethane can be fitted over the probe, such as that illustrated in FIG. 3.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of the equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

- 1. A therapeutic radiation source, comprising:
- A. a flexible catheter extending along a probe axis between a proximal end and a distal end of the catheter, the flexible catheter comprising optical delivery means extending along said probe axis and having an originating end and a terminating end, and adapted for transmitting optical radiation incident on said originating end to said terminating end;
- B. an optical source, including means for generating a beam of optical radiation directed to said originating end of said optical delivery means;
- C. a radiation source coupled to said terminating end of said optical delivery means, comprising a substantially rigid housing enclosing an electron source and a target, said housing defining a substantially evacuated interior

region extending along a beam axis between said electron source at an input end of the housing and a radiation transmissive window at an output end of the housing,

- a. wherein said electron source and said target are disposed along said beam axis and spaced apart from and opposite each other;
- b. wherein said electron source is adapted to emit electrons in response to optical radiation transmitted to said terminating end, and comprises a thermionic 10 emitter having an electron emissive surface; and
- c. wherein said target is responsive to incident electrons to emit therapeutic radiation whereby therapeutic radiation emitted therefrom is directed through the radiation transmissive window; and
- D. means for establishing an accelerating electric field extending between said electron source toward said target, the electric field acting to accelerate electrons emitted from said electron source toward said target;
- wherein said optical delivery means are adapted for directing a beam of optical radiation transmitted therethrough to impinge upon said surface of said thermionic emitter, and wherein said beam of transmitted optical radiation has a power level sufficient to heat at least a portion of said surface to an electron emitting temperature so as to cause thermionic emission of electrons from said surface.
- 2. A therapeutic radiation source according to claim 1, wherein said optical source is a laser, and wherein said beam of optical radiation is substantially monochromatic and coherent.
- 3. A therapeutic radiation source according to claim 1, wherein said therapeutic radiation comprises x-rays.
- 4. A therapeutic radiation source according to claim 1, wherein said optical delivery means comprises a fiber opti-

cal cable assembly having a fiber optical element extending from said originating end to said terminating end.

- 5. A therapeutic radiation source according to claim 4, wherein the means for establishing an accelerating electric field comprises:
  - a power supply, having a first terminal and a second terminal, and a drive means for establishing an output voltage between said first terminal and said second terminal, said power supply being electrically coupled to said radiation source by way of said first terminal and said second terminal.
- 6. A therapeutic radiation source according to claim 4, wherein said fiber optical cable assembly further comprises:
  - A. an electrically conductive cable, wherein said fiber optical element is concentrically disposed around said electrically conductive cable; and
- B. an electrically conductive outer shell, concentrically disposed around said fiber optical element, said fiber optical element forming an optically transmissive core.
- 7. A therapeutic radiation source according to claim 6, wherein said fiber optical cable assembly further comprises a first cladding shell, said first cladding shell having an index of refraction less than the index of refraction of said optically transmissive core and being concentrically disposed between said electrically conductive cable and said fiber optical element.
- 8. A therapeutic radiation source according to claim 7 wherein said fiber optical cable assembly further comprises a second cladding shell, said second cladding shell having an index of refraction less than the index of refraction of said optically transmissive core and being concentrically disposed between said fiber optical element and said electrically conductive outer shell.

\* \* \*

ADDED TO REISSUE APPLICATION	ASSERTED SUPPORT IN SPECIFICATION OF '932 PATENT	DESCRIPTION (boldface added)	FIGURES
	col. 1, lines 11-15;	"The present invention relates to a highly miniaturized, low power,	Fig.s 5 and 6
A vascular probe	col. 2, lines 17-19; col. 2, lines 27-29;	programmable radiation source and more particularly to a miniaturized radiation source mounted in a <b>flexible probe</b> ." (col. 1, lines 11-15)	illustrate a flexible probe
having an X-ray tube as a distal	col. 2, lines 32-37; col. 3, lines 25-27;	" it is desirable to have a flexible tube leading to the x-ray emitting	having an x-ray tube as a distal
इं. इंट	col. 7, lines 33-35; col. 7, line 55 – col.	target " (col. 2, lines 17-19)	end. Fig.s 5 and 6 also illustrate a
	8, line 2	" It is a further object of the present invention to provide an improved highly miniaturized radiation source with a flexible probe." (col. 2, lines	flexible optical fiber having a
length, a first electrical		27-29)	bore through its length, and an
conductor extending		" The present invention is directed to a miniaturized radiation source at the end of a flexible probe or catheter. The flexible catheter extends	electrical
through the bore		along a probe axis between a proximal end and a distal end of the catheter.	extending
of the optical fiber,		The radiation source, at the distal end of the catheter, " (col. 2, lines 32-37)	through the bore of the optical fiber.
		" the radiation source can be disposed at the distal end of the tip of a flexible tube or catheter which can be inserted into the body. In one embodiment, only a single high voltage wire is necessary for operation." (col. 3, lines 25-28)	
		"Preferably, the probe assembly includes <b>flexible fiber optical cable</b> 202 enclosed in a small-diameter flexible metallic tube 204."	

		(col. 7, lines 33-35)
		"A high voltage <b>conductor 208, embedded in the fiber optical cable 202,</b> conducts electrons to the cathode 222 The fiber optical cable 202 acts as an insulating dielectric between the <b>high voltage conductor 208</b> and the grounded flexible tube 204 the <b>fiber optic cable 202 can have an annular configuration</b> . The light from the laser 220 travels down the annular core of the fiber optic cable 202. (col. 7, line 55 – col. 8, line 2)
a second	col. 2, lines 58-59;	"The target and outer surface of the probe is preferably maintained at
conductor on the outer surface of	col. 7, lines 32-34; col. 7, line 58 - col.	ground potential to reduce the risk of shock." (col. 2, lines 58-59)
the optical fiber,	8 line 5.	" the probe assembly includes flexible fiber optical cable 202 enclosed in a small-diameter flexible metallic tube 204." (col. 7, lines 32-34)
	•	"Similarly, the flexible tube 204 couples a ground return from the target 228 to the high voltage source The fiber optical cable 202 acts as an insulating dielectric between the high voltage conductor 208 and the grounded flexible tube 204 the fiber optic cable 202 can have an annular configuration. The light travels down the annular core of the fiber optic cable 202. Cladding can be provided on each side of the core The grounded flexible metal tube 204 can surround the outer cladding."
		(col. /, line 38 – col. 8, line 5)

an essentially	Col. 2 lines 35-40:	"The radiation source, at the distal end of the catheter, includes a	
cylindrical tube	Col. 7 lines 35-51;	substantially rigid housing disposed about a substantially evacuated	
formed of		interior region extending along a beam axis from an electron source at an	
electrically		input end of the housing to a radiation transmissive window at an output	
insulative and X-		end of the housing." (col. 2, lines 35-40)	
ray transmissive			
material secured		"The radiation source assembly 226 extends from the end of the probe	
on a distal end of		assembly 214 and <b>includes a shell</b> which encloses the target 228.	•
the optical fiber,		According to one embodiment, the radiation source assembly 226 is rigid in	
the tube having a		nature and generally cylindrical in shape. In this embodiment the	
proximal end		cylindrical shell enclosing the radiation source assembly 226 can be	
secured in a		considered to provide a housing for the electron beam source as well as a	
sealed		tubular probe extending from the housing along the electron beam path."	
connection to the		The inner surface 226A of the assembly 226 is lined with an electrical	
outer wall of the		insulator,,,,. According to a preferred embodiment, the radiation	
optical fiber, at a		source assembly is hermetically sealed to the end of the probe assembly	
position spaced		214, and evacuated. According to another embodiment, the entire probe	
back from the		assembly 214 is evacuated. (col. 7, lines 35-51)	
end of the optical			
fiber, and the			
tube having a			
distal end and			
defining a		,	
vacuum chamber			
within the tube,			
a cathode	col. 3, lines 39-40;	"The x-ray source assembly 19 has an electron source (cathode) 22	
secured to the	col. 3, lines 60-63;	located in the distal end of the probe 14." (col. 3, lines 39-40)	
end of the optical	col. 7, lines 55-57;		
fiber within the		"In the various forms of x-ray source assembly 19, the electron beam	
tube, the cathode		generator 22 may include a thermionic emitter (driven by a low voltage	

first conductor in the bore of the			
the bore of the		"A high voltage conductor 208, embedded in the fiber optical cable 202,	
		conducts electrons to the cathode 222 " (col. 7, lines 55-57)	-
fiber, the cathode			
comprising a		J	
cathode which is			
excitable by heat			
to emit electrons,			
an anode formed col. 4,	col. 4, lines 58-63;	"As an example, a 0.5 mm wide electron beam is emitted at the cathode	
within the tube   col. 7,	col. 7, lines 1-3	and accelerated to 30 keV- through the anode, with 0.1 eV transverse	
near its distal		electron energies, and arrives at the target assembly 26 downstream	
end, and an		from the anode, with a beam diameter of less than 1 mm at the target	
anode conductor		assembly 26. X-rays are generated in the target assembly 26 in accordance	
connecting said		with preselected beam voltage, current, and target element 26B	
second conductor		composition." (col. 4, lines 58-63)	
from the exterior			
of the optical			
fiber to the			
anode, with an			
X-ray target in			
the path of			
electrons moving			
from the cathode			
to the anode,			
optical radiation   col. 7,	col. 7, lines 21-24;	Fig.s 5 and 6 show a diagrammatic view of radiation treatment apparatus	
	col. 3, lines 60-63;	200 including a flexible probe 214. The apparatus 200 includes a laser	
proximal end of		(or other optical) source 220 (col. 7, lines 21-24)	
the optical fiber			

optical radiation through the optical fiber, of sufficient power to heat the cathode so as to emit electrons,	•	generator 22 may include a <b>thermionic emitter (driven by a</b> low voltage
through the optical fiber, of sufficient power to heat the cathode so as to emit electrons,	-	
optical fiber, of sufficient power to heat the cathode so as to emit electrons,		power source of taser) (col. 3, IIIIes 00-03)
of sufficient power to heat the cathode so as to emit electrons,		
power to heat the cathode so as to emit electrons,		
cathode so as to emit electrons,		
emit electrons,		
7550		
Allu		
y loo	1:00.17.	
	col. 0, mics 1-7,	"X-rave are generated in the target accomply 26 in accordance with
	7:	preselected beam voltage, current, and target element 26B composition.
ower		." (col. 4, lines 63-65)
to the cathode		
and anode to		" a high voltage power supply circuit 12A for establishing a drive
establish a		voltage for the beam generator 22 an associated controller 12C
potential		establishes control of the output voltage of the high power supply circuit"
between the		(col. 5, lines 11-15)
cathode and		
anode when		" the flexible tube 204 couples a ground return from the target 228 to
desired, to		the high voltage source 219, thereby establishing a high voltage field
thereby cause X-		between the cathode 216 and the target 228." (col. 7, lines 59-62)
rays to be		
emitted		"The high voltage field between the cathode 222 and target 228
outwardly from		accelerates these electrons, thereby forcing them to strike the surface
the tube.		228A of target 228 and produce x-rays." (col. 8 lines 12-15)
	-	"The radiation source includes a substantially rigid housing
		extending to a radiation transmissive window at an output end of the
		housing The target produces x-radiation in response to incident

	accelerated free electrons." (col. 2, lines 35-49).	I. 2, lines 35-49).	
10. (New) A vascular probe according to claim 9, wherein the optical radiation means comprises a diode laser.	"In operation, the small semico optical cable 202 activates the taiode lasers are readily comme	"In operation, the small <b>semiconductor laser</b> 220 shining down the fiber optical cable 202 activates the transmissive photocathode 222 Such <b>diode lasers</b> are readily commercially available" (col. 8, lines 10-21).	
11. (New) A vascular probe according to claim 9, further including means for controlling the potential between the cathode and the anode to control the level of X-	"The high voltage power supply 12A in each of the il embodiments preferably satisfies three criteria: 1) smalefficiency to enable the use of battery power; and 3) in variable x-ray tube voltage and current to enable the programmed for specific applications. A high-frequent power converter is used to meet these requirements."  (col. 6, lines 1-7)  "The controller 12C controls the power supply 12A adjust the cathode voltage, the electron beam current parameters, or to provide pre-selected voltage, beam or	"The high voltage power supply 12A in each of the illustrated embodiments preferably satisfies three criteria: 1) small in size; 2) high efficiency to enable the use of battery power; and 3) independently variable x-ray tube voltage and current to enable the unit to be programmed for specific applications. A high-frequency, switch-mode power converter is used to meet these requirements."  (col. 6, lines 1-7)  "The controller 12C controls the power supply 12A to dynamically adjust the cathode voltage, the electron beam current, and temporal parameters, or to provide pre-selected voltage, beam current, and temporal	
ray output from the tube.	parameters. (col. 7, line 3 - col. 7, line 7)		
12. (New) A vascular probe according to claim 9, wherein the anode	Fig.s 5 and 6, and supporting description (c disclose embodiments in which the anode a elements, but the anode includes the target.	Fig.s 5 and 6, and supporting description (col. 7, line 22 - col. 8, line 42) disclose embodiments in which the anode and target are not separate elements, but the anode includes the target.	
includes the X-			

anode when desired, to thereby cause electrons to strike the target to cause X-rays to be emitted from the tube.			
14. (New) A vascular probe according to claim 13, wherein the anode includes the X-ray target.	See citations above relating to claim 9.	See description above relating to claim 9.	
15. (New) A flexible probe having an x-ray tube at its distal end, comprising: A. a flexible optical fiber adapted for transmitting optical radiation incident on a proximal end to a	col. 1, lines 11-15; col. 2, lines 17-19; col. 2, lines 32-37; col. 3, lines 25-28; col. 7, lines 33-35.	See specification text reproduced above that correspond to these citations.	

transmitted		
optical radiation		
has a power level		
sufficient to heat		
at least a portion		
of said surface to		
an electron		
emitting		
temperature so as		
to cause		
thermionic		
emission of		
electrons from		
said surface.		
17. (New)	col. 1, lines 42-55;	Col. 1, lines 42-55, col. 1, lines 57-63, and col. 6, lines 27-37 relate to
A brachytherapy	col. 1, lines 57-63;	brachytherapy and treating tumorous targets, and are reproduced below.
treatment	col. 6, lines 27-37;	The specification text corresponding to the other citations relating to claim
apparatus,		17 have already been reproduced above.
comprising:	col. 1, lines 11-15;	
<b>.</b>	col. 2, lines 17-19;	"An alternative treatment system utilizing a point source of radiation is
50	col. 2, lines 32-37;	disclosed in U.S. Pat. No. 5,153,900 issued to Nomikos et al., U.S. Pat. No.
an optical fiber	col. 3, lines 25-28;	5,369,679 to Sliski et al., and U.S. Pat. No. 5,422,926 to Smith et al., all
	col. 7, lines 33-35	owned by the assignee of the present application, all of which are hereby
transmitting		incorporated by reference. This system includes a miniaturized, insertable
optical radiation	col. 3, lines 60-63;	probe capable of producing low power radiation in predefined dose
incident on a	col. 7, lines 21-24;	geometries disposed about a predetermined location. This type of treatment
proximal end to a		is referred to as brachytherapy because the source is located close to or in
distal end;	col. 2, lines 35-40;	some cases within the area receiving treatment. One advantage of
B. an optical	col. 3, lines 39-40;	brachytherapy is that the radiation is applied primarily to treat a predefined
source for	col. 3, lines 60-63;	tissue volume, without significantly affecting the tissue adjacent to the